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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,334	11/26/2003	Barry N. Gellman	MIY-P02-010	9483

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EXAMINER

VENIAMINOV, NIKITA R

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/723,334

Applicant(s)

GELLMAN, BARRY N.

Examiner

Nikita R Veniaminov

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24-28 and 30-56 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/26/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 11/26/2003 is being considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities: The phrase "now is US Patent No.6,689,047 B2" should be inserted in Paragraph [0001], line 2 before the phrase "which". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

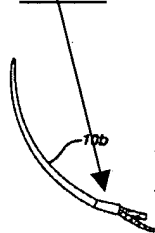
4. **Claims 24-28, 30, 31, 33-39, 41-46, 48-53, 55 and 56** are rejected under 35 U.S.C. 102(e) as being anticipated by Lehe et al. (US 6,273,852) cited by

Applicant. Lehe et al. ('852) teach a surgical device for treating urinary incontinence, comprising:

Claim 24 (independent)

a needle comprising a curved portion (10);

a dilator coupled to an end of the needle; and

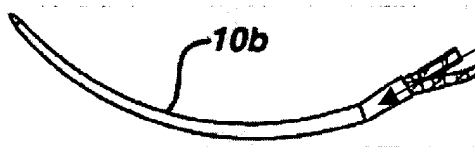


(Examiner states, that element, shown above, attached to the needle 10 will inherently enlarge or dilate the path made by the needle, since it has a conical form tapering from the end);

a sling (12) coupled to an end of the dilator (Figure 4a).

Claim 25

The surgical device of claim 24, wherein the dilator comprises a tapered leading edge.



Claim 26

The surgical device of claim 24, wherein the dilator is substantially cylindrical and tapered at one end (Examiner states, that if needle (10) has a circular cross section (column 5, lines 21-23) than, as depicted on Figure 4a, the element (20) at the end of elements 10a or 10b has circular cross section).

Claim 27

The surgical device of claim 24, wherein an outer circumference of the dilator increases from a first end of the dilator towards a second end of the dilator (see Figure below Claim 25).

Claim 28

The surgical device of claim 24, wherein a width of the dilator increases from a first end of the dilator towards a second end of the dilator (see Figure below Claim 25).

Claim 30

The surgical device of claim 24, wherein a width of the dilator is larger than a width of the needle (see Figure below Claim 25).

Claim 31

The surgical device of claim 24, wherein the sling (12) comprises a material selected from the group consisting of a natural material, a synthetic material, and a combination of a natural material and a synthetic material (column 5, lines 39-43).

Claim 33

The surgical device of claim 24 further comprising a tether (20), wherein the tether couples the needle (10) to the dilator (Figure 3a).

Claim 34

The surgical device of claim 33, wherein the tether (20) is wire (Figure 1).

Claim 35

The surgical device of claim 24 further comprising a pouch attached to the dilator (removable plastic sheath in column 6, lines 9-10).

Claim 36

The surgical device of claim 24 further comprising a pouch releasably attached to the sling (12) (removable plastic sheath in column 6, lines 9-10).

Claim 37

The surgical device of claim 24 further comprising a pouch, wherein the sling (12) is encapsulated within the pouch (removable plastic sheath in column 6, lines 9-10).

Claim 38

The surgical device of claim 37, wherein the pouch is made of a low friction material (column 6, lines 3-9).

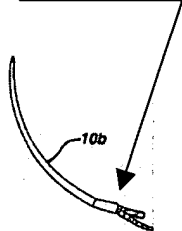
Claim 39

The surgical device of claim 37, wherein the pouch (removable plastic sheath in column 6, lines 9-10) is substantially flat (Examiner states, that the implant (12) is a tape (column 5, line 59) and the tap is flat, so the pouch, or removable plastic sheath covering said tape is flat too).

Claim 41 (independent)

an elongated member comprising a curved portion (10b);

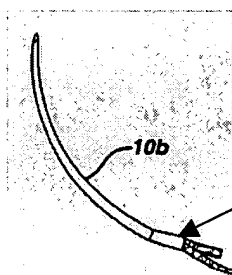
a second member, coupled to an end of the elongated member,



for enlarging an opening in a body (Examiner states, the phrase “for enlarging an opening in a body” is directed to the intended use of claiming second member, thus it does not reflect any specific structure set forth in the claim); and
an implant (12) coupled to an end of the second member (Figure 2a and column 6, lines 14-16).

Claim 42

The surgical device of claim 41, wherein the second member is substantially cylindrical (Examiner states, that if needle (10b) has a circular cross section (column 5, lines 21-23) than, as depicted on Figure 4a, the element (20) at the end of elements 10a or 10b has circular cross section) and tapered at one end



(Figure 4a).

Claim 43

The surgical device of claim 41, wherein an outer circumference of the second member increases from a first end of the second member towards a second end of the second member (see Figure below Claim 42).

Claim 44

The surgical device of claim 41, wherein a width of the second member increases from a first end of the second member towards a second end of the second member (see Figure below Claim 42).

Claim 45

The surgical device of claim 41, wherein a width of the second member is larger than a width of the elongated member (10b) (see Figure below Claim 42).

Claim 46

The surgical device of claim 41, wherein the implant (12) comprises a material selected from the group consisting of a natural material, a synthetic material, and a combination of a natural material and a synthetic material (column 5, lines 39-43).

Claim 48

The surgical device of claim 41 further comprising a tether (20) (Figure 3a), wherein the tether couples the elongated member (10b) to the second member.

Claim 49

The surgical device of claim 48, wherein the tether (20) is a wire (Figure 1).

Claim 50

The surgical device of claim 41 further comprising a pouch (removable plastic sheath in column 6, lines 9-10) attached to the second member.

Claim 51

The surgical device of claim 41 further comprising a pouch (removable plastic sheath in column 6, lines 9-10), wherein the implant is encapsulated within the pouch.

Claim 52

The surgical device of claim 51, wherein the pouch is made of a low friction material (column 6, lines 3-9).

Claim 53

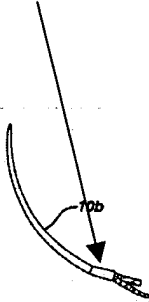
The surgical device of claim 51, wherein the pouch (removable plastic sheath in column 6, lines 9-10) is substantially flat (Examiner states, that the implant (12) is a tape (column 5, line 59) and the tap is flat, so the pouch, or removable plastic sheath covering said tape is flat too).

Claim 55

The surgical device of claim 41, wherein the elongated member (10) comprises a needle (abstract and column 4, lines 10-11).

Claim 56 (independent)

A surgical device for treating urinary incontinence, comprising;
means for creating a path through a body of a patient (10b);
means for enlarging the path created through the body of the patient ,



(Examiner states, that element attached to the needle 10b will inherently enlarge the path made by the needle, since it has a conical form tapering from the end, which connected to the needle to the end, where the tape or sling 12 is connected);
the means for enlarging the path coupled to the means for creating the path (10b); and
a sling (12) coupled to the means for enlarging the path.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 32 and 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehe et al. (US 6,273,852) cited by Applicant as applied to claims 24 and 41 above, in view of Gellman et al. (US 6,042,534) cited by Applicant. Lehe et al. ('852) teach a surgical device for treating urinary incontinence, comprising a sling or an implant, as described in paragraph 4 above. But they do not teach a sling or an implant having a width about 1 centimeter to about 3 centimeters.

Gellman et al. ('534) teach:

(Claims 32 and 47) a sling or an implant (abstract) having 1-5 centimeters in width (column 9, lines 32-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the sling or the implant of Gellman et al. ('534) with the surgical device of Lehe et al. ('852) to provide optimal size of the sling or the implant based upon anatomical considerations and the surgical procedures used to introduced and attach the sling or the implant, as taught by Gellman et al. ('534).

7. **Claims 40 and 54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehe et al. (US 6,273,852) cited by Applicant as applied to claims 24, 37, 41 and 51 above, in view of Claren et al. (US 5,899,909), cited by Applicant, and further in view of Pathak et al. (US 5,741,323). Lehe et al. ('852) teach a surgical device for treating urinary incontinence comprising (Claims 37 and 51) a pouch, wherein a sling or an implant (12) is encapsulated within the

pouch (removable plastic sheath in column 6, lines 9-10). Claren et al. ('909) teach a tape (a sling) enclosed in a thin polyethylene sheath (a pouch) (column 4, lines 49-54), which may be radiopaque or colored. But they do not teach a pouch or a sheath, wherein said pouch or sheath is translucent).

Pathak et al. ('323) teach polyethylene is a translucent material (column 17, lines 54-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the sheath of Lehe et al. ('852) with a translucent polyethylene, as taught by Pathak et al. ('323) in order to provide visualization of the sling or the implant through the sheath of Claren et al. ('909) during the implantation procedure, because polyethylene is translucent, as taught by Pathak et al. ('323).

Double Patenting

January 31, 2005. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. **Claims 24, 25, 27, 28, 29-36, 41, 43-50, 55 and 56** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1, 2, 4 and 6-13** of U.S. Patent No. 6,689,047 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in the present application are broader than claims in the patent. Therefore, any apparatus or method meeting the limitations of the patent would necessarily meet those of the claims of the application.

Allowable Subject Matter

9. **Claim 29** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

None of the prior art, either alone or in combination, teaches or suggests a surgical device for treating urinary incontinence, as claimed, wherein a dilator is about 1 centimeter to about 4 centimeters in width at a second end of the dilator.

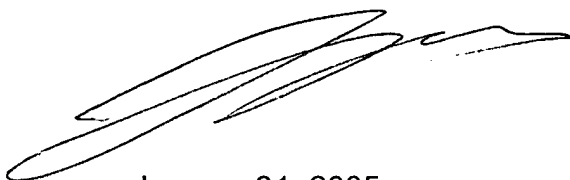
Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Staskin et al. ('977); Richmond ('516); Steckel et al. ('692); Wanderer et al. ('961); Richardson ('329); Rioux ('3916); Staskin et al. ('5774); Snitkin et al. ('2694); Suslian et al. ('211) and Pereyra ('458).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (571) 272-4735. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



January 31, 2005.

Nikita R Veniaminov
Examiner
Art Unit 3736



SAMUEL G. GILBERT
PRIMARY EXAMINER